

Introduced by Senator Torlakson

February 22, 2005

An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11165, and 11190 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 734, as amended, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would impose these requirements on any prescription for a controlled substance for use by a patient who has a terminal illness.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified

information and the applicant's fingerprints, in a manner specified by the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize ~~the board or~~ department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce the provisions relating to security printers. *An approved applicant would be required to submit an exemplar of a controlled substance prescription form, with all security features, to the department within 30 days of initial production.*

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the forms to set forth specified information, as appropriate, with respect to ~~practitioners with privileges to prescribe scheduled controlled substances, physician assistants authorized to issue a drug order, and~~ multiple prescribers.

(6) Existing law provides that with respect to specified controlled substances each dispensing pharmacy or prescriber shall provide specified information to the Department of Justice, as specified.

This bill would require the information from the dispensing pharmacy to include the method of payment for the prescription and the information from the dispensing prescriber to be provided to the department in a format set by the department *pursuant to regulation*.

(7) *Existing law provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.*

This bill would provide that the Department of Justice shall, contingent upon the availability of adequate funds, evaluate the viability of implementing real time reporting, as defined, of controlled substances in the operation of CURES.

(8) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 11159.2 of the Health and Safety Code
2 is amended to read:
3 11159.2. (a) Notwithstanding any other provision of law, a
4 prescription for a controlled substance for use by a patient who
5 has a terminal illness shall meet the following requirements:
6 (1) Contain the information specified in subdivision (a) of
7 Section 11164.
8 (2) Indicate that the prescriber has certified that the patient is
9 terminally ill by the words “11159.2 exemption.”
10 (b) A pharmacist may fill a prescription pursuant to this
11 section when there is a technical error in the certification
12 required by paragraph (2) of subdivision (a), provided that he or
13 she has personal knowledge of the patient’s terminal illness, and
14 subsequently returns the prescription to the prescriber for
15 correction within 72 hours.
16 (c) For purposes of this section, “terminally ill” means a
17 patient who meets all of the following conditions:
18 (1) In the reasonable medical judgment of the prescribing
19 physician, the patient has been determined to be suffering from
20 an illness that is incurable and irreversible.
21 (2) In the reasonable medical judgment of the prescribing
22 physician, the patient’s illness will, if the illness takes its normal
23 course, bring about the death of the patient within a period of one
24 year.
25 (3) The patient’s treatment by the physician prescribing a
26 Schedule II controlled substance pursuant to this section
27 primarily is for the control of pain, symptom management, or
28 both, rather than for cure of the illness.
29 (d) This section shall become operative on July 1, 2004.
30 SEC. 2. Section 11161 of the Health and Safety Code is
31 amended to read:
32 11161. (a) When a practitioner is named in a warrant of
33 arrest or is charged in an accusatory pleading with a felony
34 violation of Section 11153, 11154, 11156, 11157, 11170, 11173,
35 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5,

1 11379, 11379.5, or 11379.6, the court in which the accusatory
 2 pleading is filed or the magistrate who issued the warrant of
 3 arrest shall, upon the motion of a law enforcement agency which
 4 is supported by reasonable cause, issue an order which requires
 5 the practitioner to surrender to the clerk of the court all controlled
 6 substance prescription forms in the practitioner's possession at a
 7 time set in the order and which prohibits the practitioner from
 8 obtaining, ordering, or using any additional prescription forms.
 9 The law enforcement agency obtaining the order shall notify the
 10 Department of Justice of this order. Except as provided in
 11 subdivisions (b) and (e) of this section, the order shall remain in
 12 effect until further order of the court. Any practitioner possessing
 13 prescription forms in violation of the order is guilty of a
 14 misdemeanor.

15 (b) The order provided by subdivision (a) shall be vacated if
 16 the court or magistrate finds that the underlying violation or
 17 violations are not supported by reasonable cause at a hearing held
 18 within two court days after the practitioner files and personally
 19 serves upon the prosecuting attorney and the law enforcement
 20 agency that obtained the order, a notice of motion to vacate the
 21 order with any affidavits on which the practitioner relies. At the
 22 hearing, the burden of proof, by a preponderance of the evidence,
 23 is on the prosecution. Evidence presented at the hearing shall be
 24 limited to the warrant of arrest with supporting affidavits, the
 25 motion to require the defendant to surrender controlled substance
 26 prescription forms and to prohibit the defendant from obtaining,
 27 ordering, or using controlled substance prescription forms, with
 28 supporting affidavits, the sworn complaint together with any
 29 documents or reports incorporated by reference thereto which, if
 30 based on information and belief, state the basis for the
 31 information, or any other documents of similar reliability as well
 32 as affidavits and counter affidavits submitted by the prosecution
 33 and defense. Granting of the motion to vacate the order is no bar
 34 to prosecution of the alleged violation or violations.

35 (c) The defendant may elect to challenge the order issued
 36 under subdivision (a) at the preliminary examination. At that
 37 hearing, the evidence shall be limited to that set forth in
 38 subdivision (b) and any other evidence otherwise admissible at
 39 the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

SEC. 3. Section 11161.5 of the Health and Safety Code is amended to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.

(b) The department may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; and all managing general partners, if any.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, or managing general partner.

(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The department shall provide the applicant with the means and direction to provide fingerprints and related information, in a

1 manner specified by the department, for the purpose of
2 completing state, federal, or foreign criminal background checks.

3 (C) Any applicant described in subdivision (b) shall submit his
4 or her fingerprint images and related information to the
5 department, for the purpose of the department obtaining
6 information as to the existence and nature of a record of state,
7 federal, or foreign level convictions and state, federal, or foreign
8 level arrests for which the department establishes that the
9 applicant was released on bail or on his or her own recognizance
10 pending trial, as described in subdivision (I) of Section 11105 of
11 the Penal Code. Requests for federal level criminal offender
12 record information received by the department pursuant to this
13 section shall be forwarded to the Federal Bureau of Investigation
14 by the department.

15 (D) The department shall assess against each applicant a fee
16 determined by the department to be sufficient to cover all
17 processing, maintenance, and investigative costs generated from
18 or associated with completing state, federal, or foreign
19 background checks pursuant to this section with respect to that
20 applicant; the fee shall be paid by the applicant at the time he or
21 she submits fingerprints and related information to the
22 department.

23 (E) The department shall retain fingerprint impressions and
24 related information for subsequent arrest notification pursuant to
25 Section 11105.2 of the Penal Code for all applicants.

26 (c) The department may, within 60 calendar days of receipt of
27 the application from the applicant, deny the security printer
28 application.

29 (d) The department may deny a security printer application on
30 any of the following grounds:

31 (1) The applicant, any individual owner, partner, corporate
32 officer, manager, agent, representative, employee, or
33 subcontractor for the applicant, who has direct access,
34 management, or control of controlled substance prescription
35 forms, has been convicted of a crime. A conviction within the
36 meaning of this paragraph means a plea or verdict of guilty or a
37 conviction following a plea of nolo contendere. Any action
38 which a board is permitted to take following the establishment of
39 a conviction may be taken when the time for appeal has elapsed,
40 the judgment of conviction has been affirmed on appeal, or when

1 an order granting probation is made suspending the imposition of
2 sentence, irrespective of a subsequent order under the provisions
3 of Section 1203.4 of the Penal Code.

4 (2) The applicant committed any act involving dishonesty,
5 fraud, or deceit with the intent to substantially benefit himself,
6 herself, or another, or substantially injure another.

7 (3) The applicant committed any act that would constitute a
8 violation of this division.

9 (4) The applicant knowingly made a false statement of fact
10 required to be revealed in the application to produce controlled
11 substance prescription forms.

12 (5) The department determines that the applicant failed to
13 demonstrate adequate security procedures relating to the
14 production and distribution of controlled substance prescription
15 forms.

16 (6) The department determines that the applicant has
17 submitted an incomplete application.

18 (7) As a condition for its approval as a security printer, an
19 applicant shall authorize the ~~Board of Pharmacy or~~ Department
20 of Justice to make any examination of the books and records of
21 the applicant, or to visit and inspect the applicant during business
22 hours, to the extent deemed necessary by the board or department
23 to properly enforce this section.

24 (e) *An approved applicant shall submit an exemplar of a*
25 *controlled substance prescription form, with all security features,*
26 *to the Department of Justice within 30 days of initial production.*

27 (f) The department shall maintain a list of approved security
28 printers and the department shall make this information available
29 to prescribers and other appropriate government agencies,
30 including the Board of Pharmacy.

31 ~~(f)~~

32 (g) Before printing any controlled substance prescription
33 forms, a security printer shall verify with the appropriate
34 licensing board that the prescriber possesses a license and current
35 prescribing privileges which permits the prescribing of controlled
36 substances.

37 ~~(g)~~

38 (h) Controlled substance prescription forms shall be provided
39 directly to the prescriber either in person, by certified mail, or by

1 a means that requires a signature signifying receipt of the
2 package and provision of that signature to the security printer.

3 ~~(h)~~

4 (i) Security printers shall retain ordering and delivery records
5 in a readily retrievable manner for individual prescribers for three
6 years.

7 ~~(i)~~

8 (j) Security printers shall produce ordering and delivery
9 records upon request by an authorized officer of the law as
10 defined in Section 4017 of the Business and Professions Code.

11 ~~(j)~~

12 (k) (1) The department may revoke its approval of a security
13 printer for a violation of this division or action that would permit
14 a denial pursuant to subdivision (d) of this section.

15 (2) When the department revokes its approval, it shall notify
16 the appropriate licensing boards and remove the security printer
17 from the list of approved security printers.

18 SEC. 4. Section 11162.1 of the Health and Safety Code is
19 amended to read:

20 11162.1. (a) The prescription forms for controlled substances
21 shall be printed with the following features:

22 (1) A latent, repetitive “void” pattern shall be printed across
23 the entire front of the prescription blank; if a prescription is
24 scanned or photocopied, the word “void” shall appear in a pattern
25 across the entire front of the prescription.

26 (2) A watermark shall be printed on the backside of the
27 prescription blank; the watermark shall consist of the words
28 “California Security Prescription.”

29 (3) A chemical void protection that prevents alteration by
30 chemical washing.

31 (4) A feature printed in thermo-chromic ink.

32 (5) An area of opaque writing so that the writing disappears if
33 the prescription is lightened.

34 (6) A description of the security features included on each
35 prescription form.

36 (7) (A) Six quantity check off boxes shall be printed on the
37 form and the following quantities shall appear:

38 1-24

39 25-49

40 50-74

1 75-100
2 101-150
3 151 and over.

4 (B) In conjunction with the quantity boxes, a space shall be
5 provided to designate the units referenced in the quantity boxes
6 when the drug is not in tablet or capsule form.

7 (8) Prescription blanks shall contain a statement printed on the
8 bottom of the prescription blank that the “Prescription is void if
9 the number of drugs prescribed is not noted.”

10 (9) (A) The preprinted name, category of licensure, license
11 number, federal controlled substance registration number of the
12 prescribing practitioner.

13 ~~(B) The privileges of a practitioner to prescribe any of the~~
14 ~~following controlled substances shall be preprinted beside the~~
15 ~~prescriber’s name and as designated in the prescriber’s certificate~~
16 ~~issued by the federal Drug and Enforcement Agency:~~

- 17 ~~(i) Schedule II narcotic.~~
- 18 ~~(ii) Schedule II nonnarcotic.~~
- 19 ~~(iii) Schedule III narcotic.~~
- 20 ~~(iv) Schedule III nonnarcotic.~~
- 21 ~~(v) Schedule IV.~~
- 22 ~~(vi) Schedule V.~~

23 (10) A check box indicating the prescriber’s order not to
24 substitute.

25 (11) An identifying number assigned to the approved security
26 printer by the Department of Justice.

27 ~~(12) A physician assistant authorized by Section 3502.1 of the~~
28 ~~Business and Professions Code to issue a drug order may do so~~
29 ~~under his or her own name on prescription forms preprinted with~~
30 ~~the information required by Section 11162 that are in compliance~~
31 ~~with subdivision (d) of Section 3502.1 of the Business and~~
32 ~~Professions Code.~~

33 (b) Each batch of controlled substance prescription forms shall
34 have the lot number printed on the form and each form within
35 that batch shall be numbered sequentially beginning with the
36 numeral one.

37 (c) (1) A prescriber designated by a licensed health care
38 facility may order controlled substance prescription forms for use
39 by prescribers when treating patients in that facility without the

1 information required in paragraph (9) of subdivision (a) *or*
2 *paragraph (3) of this subdivision.*

3 (2) Forms ordered pursuant to this subdivision shall have the
4 name, category of licensure, license number, and federal
5 controlled substance registration number of the designated
6 prescriber and the name, address, category of licensure, and
7 license number of the licensed health care facility preprinted on
8 the form.

9 (3) (A) Forms ordered pursuant to this subdivision that list
10 multiple prescribers on one prescription form shall have a check
11 box by the name of each designated prescriber.

12 (B) Each designated prescriber who signs the prescription
13 form shall identify himself or herself as the prescriber by
14 checking the box by the prescriber's name.

15 (4) Forms ordered pursuant to this section shall not be valid
16 prescriptions without the name, category of licensure, license
17 number, and federal controlled substance registration number of
18 the prescriber on the form.

19 (5) (A) The designated prescriber shall maintain a record of
20 the prescribers to whom controlled substance prescription forms
21 are issued.

22 (B) The record shall include the name, category of licensure,
23 license number, federal controlled substance registration number,
24 and the quantity of controlled substance prescription forms
25 issued to each prescriber; the record shall be maintained in the
26 health facility for three years.

27 (d) This section shall become operative on July 1, 2004.

28 SEC. 5. Section 11165 of the Health and Safety Code is
29 amended to read:

30 11165. (a) To assist law enforcement and regulatory agencies
31 in their efforts to control the diversion and resultant abuse of
32 Schedule II and Schedule III controlled substances, and for
33 statistical analysis, education, and research, the Department of
34 Justice shall, contingent upon the availability of adequate funds
35 from the Contingent Fund of the Medical Board of California, the
36 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
37 Board of Registered Nursing Fund, and the Osteopathic Medical
38 Board of California Contingent Fund, maintain the Controlled
39 Substance Utilization Review and Evaluation System (CURES)
40 for the electronic monitoring of the prescribing and dispensing of

1 Schedule II and Schedule III controlled substances by all
2 practitioners authorized to prescribe or dispense these controlled
3 substances.

4 (b) The reporting of Schedule III controlled substance
5 prescriptions to CURES shall be contingent upon the availability
6 of adequate funds from the Department of Justice. The
7 Department of Justice may seek and use grant funds to pay the
8 costs incurred from the reporting of controlled substance
9 prescriptions to CURES. Funds shall not be appropriated from
10 the Contingent Fund of the Medical Board of California, the
11 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
12 Board of Registered Nursing Fund, or the Osteopathic Medical
13 Board of California Contingent Fund to pay the costs of reporting
14 Schedule III controlled substance prescriptions to CURES.

15 (c) CURES shall operate under existing provisions of law to
16 safeguard the privacy and confidentiality of patients. Data
17 obtained from CURES shall only be provided to appropriate
18 state, local, and federal persons or public agencies for
19 disciplinary, civil, or criminal purposes and to other agencies or
20 entities, as determined by the Department of Justice, for the
21 purpose of educating practitioners and others in lieu of
22 disciplinary, civil, or criminal actions. Data may be provided to
23 public or private entities, as approved by the Department of
24 Justice, for educational, peer review, statistical, or research
25 purposes, provided that patient information, including any
26 information that may identify the patient, is not compromised.
27 Further, data disclosed to any individual or agency as described
28 in this subdivision shall not be disclosed, sold, or transferred to
29 any third party.

30 (d) For each prescription for a Schedule II or Schedule III
31 controlled substance, the dispensing pharmacy shall provide the
32 following information to the Department of Justice in a
33 frequency and format specified by the Department of Justice:

34 (1) Full name, address, gender, and date of birth of the patient.

35 (2) The prescriber's category of licensure and license number;
36 federal controlled substance registration number; and the state
37 medical license number of any prescriber using the federal
38 controlled substance registration number of a
39 government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

~~(9) Method of payment for prescription.~~

(e) (1) The Department of Justice shall, contingent upon the availability of adequate funds, evaluate the viability of implementing real time reporting of controlled substances in the operation of CURES.

(2) For the purposes of this subdivision, "real time reporting" means ____.

(f) This section shall become operative on January 1, 2005.

SEC. 6. Section 11190 of the Health and Safety Code is amended to read:

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

1 (C) NDC (National Drug Code) number of the controlled
2 substance dispensed.

3 (D) Quantity of the controlled substance dispensed.

4 (E) ICD-9 (diagnosis code), if available.

5 (F) Date of dispensing of the prescription.

6 (2) Each prescriber that dispenses controlled substances shall
7 provide the Department of Justice the information required by
8 this subdivision on a monthly basis in a format set by the
9 Department of Justice *pursuant to regulation*.

10 (d) This section shall become operative on January 1, 2005.

11 SEC. 7. No reimbursement is required by this act pursuant to
12 Section 6 of Article XIII B of the California Constitution for
13 certain costs that may be incurred by a local agency or school
14 district because, in that regard, this act creates a new crime or
15 infraction, eliminates a crime or infraction, or changes the
16 penalty for a crime or infraction, within the meaning of Section
17 17556 of the Government Code, or changes the definition of a
18 crime within the meaning of Section 6 of Article XIII B of the
19 California Constitution.

20 However, if the Commission on State Mandates determines
21 that this act contains other costs mandated by the state,
22 reimbursement to local agencies and school districts for those
23 costs shall be made pursuant to Part 7 (commencing with Section
24 17500) of Division 4 of Title 2 of the Government Code.